

A Message From the Director

Hello. My name is Elizabeth Cotsworth and I am the new Director of the Office of Radiation and Indoor Air (ORIA). Prior to joining ORIA, I was the Director of EPA's Office of Solid Waste where I managed the Agency's national hazardous and solid waste programs. I want you to know that one of my highest priorities is making sure that radioactive waste is safely stored, disposed, and managed at the WIPP. EPA continues to ensure the Department of Energy (DOE) complies with our standards and that the WIPP safely contains transuranic waste. We do this by inspecting the WIPP facility and DOE's transuranic waste generator sites. We are also working very hard preparing for the WIPP recertification process; we expect to receive DOE's first recertification application by March 2004.

I also want to take this opportunity to reaffirm EPA's commitment to keep you informed about our continuing oversight role and activities for the WIPP. I feel that it is important that you understand how we do our job and why we make the decisions we make. My staff and I care about what you think and are open to responding to your questions and concerns. Please feel free to contact us either by: sending your questions and comments by email to: radiation.questions@epa.gov; leaving a message on our WIPP Information Line, 1-800-331-WIPP; or sending your questions and comments by U.S. mail to: Betsy Forinash, Director, WIPP Program, Office of Radiation and Indoor Air, Mailcode 6608J, 1200 Pennsylvania Avenue, NW, Washington, DC 20460.

Office of Radiation and Indoor Air (6608J)
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Focus On Recertification

What is Recertification?

It is a process to reaffirm that the WIPP continues to meet all the requirements of EPA's disposal regulations. The recertification process will ensure that the WIPP is operated using the most accurate, up-to-date information available and provides documentation requiring DOE to operate by to these standards. Recertification is not a reconsideration of the decision to open WIPP. EPA is required by law to evaluate all changes in conditions or activities at WIPP every five years to determine if WIPP continues to comply with our disposal regulations. The first of these recertifications occurs in 2004 and will include a review of all of the changes made at the WIPP facility since our initial certification decision in 1998.

Since our initial certification decision in 1998, we have been conducting independent technical reviews and inspections annually of all WIPP activities related to compliance with our disposal regulations. EPA reviews all changes in activities or conditions and may modify, suspend or revoke certification at any time to prevent or quickly reverse a potential danger to public health. Recertification evaluates changes at the WIPP.

The 1998 Certification identified the starting (baseline) conditions for the WIPP site and established the waste and facility characteristics necessary to ensure proper disposal in accordance with our disposal regulations. At that time, EPA and DOE understood that future information and knowledge gained from the actual operations of the WIPP would result in changes to the best practices and procedures for the facility. In recognition of this, EPA is required by law to evaluate all changes in conditions or activities at WIPP every five years to determine if WIPP continues to comply with our disposal regulations. The first of these recertifications occurs in 2004 and will include a review of all of the changes made at the WIPP facility since our initial certification decision in 1998.

DOE will apply for recertification.

While EPA has been tracking all changes at the WIPP, during recertification, we will conduct a more in-depth look at the collective effect of changes DOE made in WIPP operations over the last five years. As part of this recertification, DOE is required to produce a new performance assessment in order to evaluate changes to the facility and the environment and to reaffirm that the WIPP continues to meet all of EPA's disposal regulations requirements. Additionally, DOE must submit a "Recertification Application" to EPA containing the results of the performance assessment and identifying all changes and updates to the WIPP. EPA must receive the application no later than March 2004 (five years from when waste was first received at the WIPP).

EPA will review DOE's application.

Once EPA determines that the application is complete, we must make a decision on recertification within six months. The focus of our review will be on areas of change identified by DOE, in order to ensure that their cumulative effects have been adequately addressed. Areas that DOE states have not changed will be reviewed by EPA to verify that they have not. DOE must demonstrate that it meets all aspects of the Agency's disposal regulations. When we determine that we have received a complete Recertification Application from DOE, we have six months from that date to make our recertification decision. We will notify DOE of our decision in the Federal Register and, if we approve DOE's Recertification Application, it will serve as the new "baseline" for the next WIPP recertification in 2009.

The public is invited to comment.

EPA welcomes and encourages public involvement in the recertification process. We are most interested in public comment on any issues or changes where changes have occurred which that may potentially impact the WIPP's ability to remain in compliance with the requirements in our disposal regulations, as well as any areas where the public believes that changes have occurred and have not been identified by DOE.

EPA will make information available to the public.

EPA will place all DOE submissions in the public docket and will solicit public comments on DOE's Recertification Application. EPA will also make sure that key information, including DOE's application, will be available on our website at: www.epa.gov/radiation/wipp/ and in our dockets. And, we will establish clear procedures for submitting comments will be outlined as well. We plan to meet informally with stakeholders during our review to discuss issues of interest in the application.

After we determine we have received a complete Recertification Application from DOE and before making our recertification decision, EPA staff will meet informally with key stakeholders to discuss any issues of concern. We will post our recertification decision on our EPA WIPP website, announce our decision via email to interested stakeholders, publish our decision in the Federal Register, and write an article summarizing our decision for inclusion in a future next issue of the EPA WIPP Bulletin.

Recertification of the WIPP Facility

This provides an overview of EPA's recertification process for the WIPP that will take place in 2004.

What is Recertification?

EPA is required by law to evaluate all changes in conditions or activities at WIPP every five years to determine if WIPP continues to comply with EPA's disposal regulations for the facility. The first of these recertifications will occur in 2004 and will include a review of all of the changes made at the WIPP facility since the original 1998 EPA certification. It is not a reconsideration of the decision to open WIPP, but a process to reaffirm that the WIPP meets all requirements of the disposal regulations. The recertification process will not be used to approve any new significant changes proposed by DOE; any such proposals will be addressed separately by EPA. Based on our review of annual change reports, EPA does not anticipate any issues that would prevent recertification in 2004. However, recertification ensures that the WIPP is operated using the most accurate and up-to-date information available and provides documentation requiring DOE to operate to these standards.

EPA Reviews Changes at the WIPP Annually

Since the 1998 certification, EPA has been conducting independent technical review and inspections of all WIPP activities related to compliance with EPA's WIPP disposal regulations. EPA reviews all changes in activities or conditions and may modify, suspend or revoke certification at any time to prevent or quickly reverse a potential danger to public health.

The 1998 certification identified the starting (baseline) conditions for the WIPP site and established the waste and facility characteristics necessary to ensure proper disposal in accordance with the regulations. At that time, EPA and DOE understood that future information and knowledge gained from the actual operations of the WIPP would result in changes to the best practices and procedures for the facility. As such, a process for identifying and evaluating these changes was established. Key elements of this process are:

- All potentially significant changes are proposed for EPA approval before they are implemented by DOE.
- DOE submits annual change reports to EPA that identify all changes, both significant and minor, that were made to WIPP operations or plans during the preceding year.
- EPA reviews all changes to ensure we have no concerns regarding the performance of the WIPP or DOE's continuing compliance with disposal regulations.

Recertification is a More In-Depth Look at Changes

Every five years, EPA conducts a recertification of the WIPP to review and conduct a more in-depth look at the collective effect of changes made in the WIPP operations. As part of this recertification:

- DOE is required to conduct a new performance assessment in order to evaluate changes to the facility and the environment and to reaf-

firm that the WIPP meets all requirements of EPA's disposal regulations.

- DOE submits a recertification application to EPA containing the results of the performance assessment and identifying all changes and updates to the WIPP.
- EPA reviews this application in detail to assure that the WIPP will continue to safely contain transuranic radioactive waste.
- An approved application becomes DOE's commitment for how WIPP will be operated over the following five years. This application will then serve as the baseline for the next recertification in 2009.

Process and Schedule

- By law, DOE is required to submit a recertification application to EPA by March 2004 (five years from the first receipt of waste at the WIPP).
- EPA will review the application for completeness and work with DOE to ensure that a complete application is received.
- EPA is required to reach a recertification decision within six months of receipt of a complete application.
- EPA will focus its review on areas of change identified by DOE, in order to ensure that their effects have been addressed. Areas that have not been changed will be reviewed to verify that they have not changed. DOE must demonstrate that it meets all aspects of the disposal regulations before EPA will approve recertification.

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- EPA will base its recertification decision on the results of its ongoing oversight of the WIPP and on DOE's application. At that point, EPA will submit a letter to DOE announcing its decision.

How can you get involved?

- EPA will place all DOE submittals in the public docket and will solicit public comments on DOE's application. EPA will make sure that key information is available on the web and at EPA dockets and establish clear procedures for submitting comments.
- EPA will be most interested in public input on issues where changes have occurred which may have a potential impact on the WIPP's ability to remain in compliance with our disposal regulations, as well as any areas where the public believes that changes have occurred at WIPP that have not been identified by DOE.
- EPA staff will meet with stakeholders after receiving DOE's application to discuss issues of concern to the public before we make a final decision.
- EPA will share its decision with the public through an announcement emailed to interested stakeholders, the EPA WIPP website and a notice in the Federal Register. To be added to our email list, please send an email to ferguson.rafaela@epa.gov

Focus On Remote-Handled Waste

DOE Seeks Approval for Remote-Handled Transuranic Waste

The EPA is making a preliminary decision that is the first step in implementing disposal of remote-handled transuranic (RH-TRU) waste that was previously approved as part of the waste disposal inventory for the Waste Isolation Pilot Plant (WIPP). Remote-handled waste requires special handling and modified waste characterization procedures because, unlike most WIPP waste, its radioactivity is not effectively shielded by the waste containers. In EPA's 1998 Certification Decision (which allowed WIPP to open), the Agency examined the amount and type of remote-handled waste that were projected to be disposed in the WIPP. The performance assessment and verification conducted for the certification demonstrated that the WIPP can safely contain RH-TRU waste. However, RH-TRU waste has not been disposed at WIPP since its opening. Before RH-TRU waste may be placed in WIPP for disposal, EPA requires the Department of Energy (DOE) to demonstrate that generator sites can adequately characterize and track RH waste.

Preliminary Approval of Framework for Characterization of Remote-Handled Waste

After years of development, with input from EPA, DOE is now requesting EPA's approval of its plan to characterize remote-handled transuranic waste. This is DOE's first step towards disposing of RH waste in the WIPP. This plan is comprised of two documents: the RH Transuranic Waste Characterization Plan and the Waste Characterization Program Implementation Plan (WCPIP), Revision 0D.

EPA's December 19, 2003 letter to DOE outlines our preliminary decision to approve the RH Waste Characterization Plan and Implementation Plan. It also describes the approval process for waste generator sites to characterize RH waste for disposal at WIPP. The letter, Waste Characterization Plan, and Implementation Plan are available online in Adobe .pdf format—please check our website (<http://www.epa.gov/radiation/wipp>) for more details.

EPA believes that DOE's Waste Characterization Plan and Implementation Plan provide an appropriate general framework for conducting RH waste characterization activities. We are proposing to approve both plans, which would allow DOE to proceed with developing site-specific characterization plans for RH waste. This proposed approval does not authorize DOE to characterize or ship RH waste to the WIPP.

Future Approvals for Waste Generator Sites to Implement RH Waste Characterization

In order to obtain authorization from EPA to conduct RH waste characterization, shipment and disposal from waste generator sites, DOE must submit documentation specific to each of the waste generator sites to show the requirements in the Waste Characterization Plan and Implementation Plan have been fully met. Each site must also be inspected by EPA to evaluate whether it is adequately implementing the site-specific RH waste characterization programs. The Agency will follow the 40 CFR 194.8 or 194.24 inspection process as appropriate. EPA will make the site-specific waste characterization plans and inspection reports available in the WIPP dockets and on its website. The website will also announce opportunities for public comment on our waste characterization activities. You

can also choose to be notified by e-mail of our future inspections—including those related to remote-handled waste—by subscribing to EPA's WIPP-NEWS update service.

EPA's WIPP Team is committed to a thoughtful, transparent process with the public. Until January 30, 2004, we are asking for your comments on our decision to approve the general framework for RH waste characterization (DOE's RH WC Program Plan and RH WCPIP [Revision 0D]). We are interested in your views on whether the Waste Characterization Plan and Implementation Plan address the necessary components of waste characterization, taking into account worker exposures to radiation and other relevant factors. We also solicit your comments on whether the site-specific approval process contains appropriate controls, and your suggestions for any additional information EPA should require in site-specific documentation. We remind you that our preliminary decision relates to characterization of RH-waste; we are not reconsidering the decision to allow remote-handled waste as part of the WIPP inventory. Based on your comments, we may revise our preliminary conclusion or request further information. Following the consideration of comments and any additional information, the Agency will issue another letter to DOE notifying them of our final decision regarding the RH Waste Characterization Plan and Implementation Plan. The letter will be made available to the public in our docket (insert number) and on the WIPP website.

You can submit your comments to EPA (via regular mail) to: Ray Lee, U.S. Environmental Protection Agency, 1200 Pennsylvania Avenue, NW, Mail Code 6608J, Washington, DC 20460. Comments (as regular text, Microsoft Word or WordPerfect documents) may

EPA's WIPP Activities

2004

Spring

- EPA Receives Recertification Application
- EPA Solicits/Receives Public Comments on Application
- Stakeholder Meetings

Summer

- EPA Public Hearings/Workshop

Fall

- EPA Reviews/Considers Public Comments
- EPA Conducts Technical Evaluation

By Year's End 2004

- EPA Issues WIPP Recertification Decision

For More Information About the WIPP

More information on EPA's continued activities concerning the WIPP can be obtained from any of EPA's five public dockets (Washington DC, and Albuquerque, Carlsbad, and Santa Fe, New Mexico). The Docket number for EPA's recertification activities at the WIPP is A-98-49. The pre-certification and certification decision Docket is A-93-02. For the latest information on EPA activities regarding the WIPP, please call EPA's recorded WIPP Information Line at 1-800-331-WIPP.

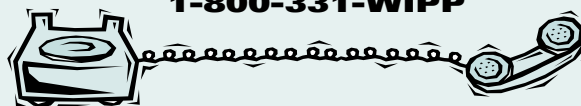
You can also read all about EPA's WIPP Program on the Internet. EPA's WIPP Homepage is an excellent source for current information on EPA's WIPP activities. From the Homepage you can also download EPA documents and docket information. EPA's WIPP Homepage address is:

www.epa.gov/radiation/wipp/

For Further Information on EPA's WIPP Activities

Please Call the WIPP Information Line

1-800-331-WIPP



or visit our website at:

<http://www.epa.gov/radiation/wipp>

also be submitted via e-mail to lee.raymond@epa.gov or faxed to 202-343-2305.

Note: EPA will be conducting the first recertification of WIPP in 2004. Although DOE may submit new infor-

mation regarding the RH inventory of waste, the process for considering RH waste characterization will adhere to any approved plans. We do not expect to approve changes to these RH plans as part of the recertification process.

WIPP-NEWS E-mail Updates!

2004 will be a very busy year for EPA and the WIPP. Aside from this year's WIPP Bulletin, we have set up an electronic update service entitled "WIPP-NEWS" to keep you informed about EPA's WIPP-related efforts. We will send out periodic e-mail updates to any interested subscribers on current topics such as recertification and ongoing inspection activities.

To subscribe to WIPP-NEWS, please send a blank e-mail message (no subject line or text) to:

wipp-news-subscribe@lists.epa.gov

Subscription details and other additional information on the WIPP-NEWS e-mail service will be posted on our website (<http://www.epa.gov/radiation/wipp>) as well.

Update on EPA's New Electronic Docket (E-DOCKET)

In the last WIPP Bulletin, we announced that EPA's new electronic docketing system, E-DOCKET (<http://www.epa.gov/edocket>), was available for use by the Agency and the general public. Here is a review of the new system, as well as some updates on EPA's WIPP-related dockets.

Anyone may use E-DOCKET to access an index of all available public dockets and view current documents in Adobe's portable data file (PDF) format. E-DOCKET users can search for a particular docket or document by title, release date, document type, Federal Register citation, program office, or other various identifiers. You can submit comments electronically as well. After identifying the docket or document on which you wish to comment and agreeing to a privacy and disclaimer notice, you may submit your comments online (using an electronic form provided on E-DOCKET) or attach comments as an electronic file. Providing your name, group, or organization is optional. After comments have been submitted, you will receive a confirmation notice. Following a mandatory review by docket staff (to screen for pro-

fanity and other obscene material) your comment will be published on E-DOCKET within three business days after receipt.

EPA currently maintains four dockets for the WIPP program:

- A-92-56, which contains information about the WIPP compliance criteria;
- A-93-02, which contains information considered in making the WIPP certification decision;
- A-98-49, which contains new information that the EPA is continuously reviewing as part of the Agency's ongoing oversight role at the WIPP; and
- E-DOCKET #OAR-2002-0005, which contains information regarding our proposed alternative provisions to 40 CFR Part 194.

Dockets A-92-56 and A-93-02 are closed and are not available on the E-DOCKET system. Hard copies of all materials contained in A-92-56 and A-93-02 are maintained at each of our docket locations in Albuquerque and Santa Fe, NM, as well as our official docket headquarters here in Washington, DC.

We are still adding documents to the index for Docket A-98-49, which includes inspection reports, letters, technical guidance, and other correspondence related to the WIPP. In addition to the paper copies that are housed in each of the docket locations listed above, these documents can be viewed online. The E-DOCKET ID for Docket A-98-49 is #OAR-2001-0012. Because the EPA docket staff is still in the process of back scanning material for all active dockets, searching this particular E-DOCKET will bring up only a partial list of documents. We expect the E-DOCKET for #OAR-2001-0012 to be complete sometime in early 2004.

EPA also has established an E-DOCKET site for materials related to its recent WIPP-related rulemaking—the alternative provisions to 40 CFR Part 194. Although the comment period for this proposed rule has closed, interested parties can still view this docket and its contents (including a Background Information Document [BID], redline/strikeout rule language comparison, comments submitted online, and other relevant materials) by searching for E-

DOCKET #OAR-2002-0005. Hard copies of these materials can also be found in Docket A-98-49, in categories VI-A, VI-B, VI-C, and VI-D The New. EPA is anticipating the final rule to be completed in early 2004. A separate E-DOCKET will be established for this final rule.

For more information or any other issues regarding E-DOCKET, please refer to EPA's E-DOCKET website at <http://www.epa.gov/edocket> or contact Shivani Desai by phone (202-566-1674) or e-mail (For WIPP-related docket matters, please contact Ray Lee at 202-564-7738).

WIPP Transportation Information* Contacts and On-Line Resources

WIPP Facility TRU Waste Transportation

Dennis Hurtt
U.S. Department of Energy
Office of Public Affairs
(505) 234-7327
www.wipp.carlsbad.nm.us

National Transportation Program
www.ntp.doe.gov

Transportation Issues

Anne Clarke
Coordinator of New Mexico's Radioactive
Waste Task Force, State of New Mexico
(505) 476-3224
www.emnrd.state.nm.us/wipp

Richard Swedberg
Health Physicist
U.S. Department of Transportation
(303) 969-6744, ext. 0363
www.fhwa.dot.gov/omc/omchome.html

Ron Ross
Program Manager
Western Governors' Association
(303) 623-9378
www.westgov.org/wipp

Kristin Marsteller
National Safety Council
(202) 293-2270, ext. 469
www.nsc.org/ehc/wipp.htm

**EPA does not regulate waste transportation to WIPP, however, we receive many requests for this information.*

Making Experience Count

Waste Characterization Inspection Process

In our July 2002 bulletin, we discussed EPA's proposed changes to the WIPP Compliance Criteria. We're applying over four years of oversight experience to improve our inspections program and approval process.

EPA issued the proposed rulemaking entitled "Criteria for the Certification and Recertification of the Waste Isolation Pilot Plant's Compliance with the Disposal Regulations; Alternative Provisions" (67 FR 51930-51946) on August 9, 2002. Foremost among the proposed changes were changes to the approval process for waste characterization programs at Department of Energy transuranic (TRU) waste generator sites. Other proposed changes would add a process for making future minor changes to the Compliance Criteria, allow for the submission of copies of compliance applications and reference materials in a non-paper format (e.g., compact disk); and update terminology related to waste characterization.

A 90-day comment period was announced in the Federal Register, and public hearings were held in Albuquerque and Santa Fe, New Mexico, on September 24-25, 2002. After considering all comments (which will be addressed in our upcoming "Response to Comments" document), EPA is now moving forward with the final rule, and expects to issue the new Compliance Criteria provisions in early 2004.

Most of the comments on our proposal related to changes in the DOE waste generator site inspection and approval process, so we'd like to provide some information on the proposed process that we expect will be finalized and begin being implemented this fall. The process will be as follows:

- EPA will conduct inspections at all new waste generator sites and previously approved sites to establish a baseline standard for waste characterization. EPA inspectors will evaluate equipment, procedures, and personnel training/experience related to a range of waste characterization components. After an inspection, EPA produces an inspection report to describe its findings. Findings that a specific item or activity is deemed inadequate usually require action by DOE to correct the problem and take steps to ensure it does not recur. If the WC processes inspected are adequate to characterize waste for disposal at WIPP, EPA will issue a "baseline approval" that allows the site to dispose of waste at WIPP (once shipping and other requirements are met).
- The baseline approval will specify any limitations on waste characterization or disposal (such as restrictions on what waste streams may be disposed) and assign specific reporting requirements for all waste characterization components and related activities. These changes and/or expansions will be assigned to one of two categories ("tiers"), depending on the required level of notification and approval outlined in the site's initial baseline approval. Tier 1 waste characterization activities at a site will have more stringent reporting requirements (e.g., require notification by DOE and approval by EPA prior to shipment of waste to the WIPP) and will most likely require additional inspections whenever any changes to that activity are made. Tier 2 activities will have more moderate reporting requirements and EPA may approve changes to certain activities without a follow-up inspection (i.e., desktop review and approval of certain technical documents). We will specify the limitations associated with the assigned tier and suggest the type of information needed for EPA review.
- EPA will issue a Federal Register notice after each of the initial baseline inspections. The public will be asked to comment on the proposed tier levels and reporting requirements for each of the waste generator sites. EPA will post relevant information and other updates concerning these decisions on the WIPP website.
- DOE will report any changes in equipment, processes, or personnel, based on their tier level, and certain changes must be reported to EPA before their implementation. EPA will then decide whether or not a follow-up inspection is necessary to confirm and verify the adequacy of any changes to the site's waste characterization program. EPA may also conduct unannounced site inspections of items not assigned to a tier if EPA determines a need based on the available information. Follow-up inspections will be posted on the WIPP website and inspection reports will be sent to our WIPP dockets.
- After a site has been approved and has an established baseline, EPA may decide to change the tiering scheme for a particular waste characterization component or activity. The decision to revise tiers at a site will be made through continued compliance inspections under the authority of § 194.24(h). In the event of this type of tier change, the Agency will notify the public in the following manner:
- EPA will announce the proposed tier change(s) and the reasoning behind them in an inspection report.
- Elevating an activity to a more stringent tier (i.e., additional DOE reporting requirements for that particular waste characterization component or activity) will be effective immediately and the site will be expected to operate under the more stringent requirements without delay.
- Before moving an activity to a less stringent tier, EPA will solicit public comment. The site will continue to operate under the more stringent tier designation until public comment can be considered. The basis to change the level of oversight for an activity (i.e., tier designation) will be described in our inspection report.

Nuclear Quality Assurance Audits

One important function of EPA audits and inspections is to ensure DOE compliance with EPA's quality assurance (QA) requirements. In the WIPP Compliance Criteria (40 CFR 194), EPA required DOE to establish rigorous QA programs to help assure that sound data and information are used in operating WIPP and evaluating its performance. Under our rules, DOE's QA programs must meet the national Nuclear Quality Assurance (NQA) standards developed by the American Society of Mechanical Engineers to be applied to nuclear facilities throughout the United States.

What is the purpose of the EPA's quality assurance audits?

Basically, the NQA standards require that each nuclear facility have an on-site organization that constantly monitors the quality of operations at the site. These organizations must have sufficient independence, authority and qualifications to effectively carry out their role. Since 1997, the EPA has conducted more than forty audits of WIPP-related facilities to confirm the proper application of the NQA standards.

What is the scope of the EPA's quality assurance audits?

The NQA standards apply for all items and activities that are important to the containment of transuranic (TRU)-waste within the WIPP. This excludes activities such as the transportation of the waste to the WIPP site, or the containment of non-radioactive hazardous wastes within the WIPP. Therefore, the scope of the EPA's QA audits is limited to the application of NQA standards that pertain to the containment of TRU-waste at the WIPP.

What does EPA do during a QA audit?

At each WIPP-related facility, the EPA's audit team reviews documents, including organizational charts, operating procedures, test results, training records, procurement records, inspection reports, and approval forms; and interviews QA

staff and management to verify compliance with the NQA standards. A facility's QA Plan is reviewed to verify that the requirements of the NQA standards are properly established within the plan. Then, the EPA auditors verify that these established requirements are properly implemented by the facility.

During an audit, the EPA's team develops a list of findings and concerns. A finding is a determination that a specific item or activity does not meet a requirement under the NQA standards. A concern is a judgment that a finding may occur in the future. Near the end of the audit, the team discusses the severity of each finding to assess its impact on the facility's QA Program.

What comes out of an audit?

The EPA team evaluates audit results and decides whether or not a facility's QA Program is in compliance. The EPA then writes an audit report. The report lists the information reviewed by EPA, describes all finding or concerns, and specifies what follow-up actions are necessary by DOE to correct any problems. Depending on the nature and severity of problems, EPA may conduct additional audits soon afterwards to further assess a finding or to verify that a finding has been corrected. In other cases, we require DOE to provide written responses to our report, documenting how problems have been addressed.

What does EPA provide to the public?

Before the first audit of a facility, the facility's QA Plan is made available to the public through the Agency's public dockets. After every audit, QA audit reports are also placed in the public docket. QA audit reports can be found in Docket A-98-49, Category II-A1. Technical documents related to QA programs can also be found in Category II-A2. [Refer to the EDOCKET article in this bulletin for more info on our dockets.]

Tracking and Understanding DOE's WIPP Changes: DOE's Annual Change Report

The DOE frequently adjusts WIPP plans and activities to increase efficiency, reflect new priorities, or address new information. EPA tracks and evaluates such changes to make sure they don't adversely affect WIPP's ability to contain radioactive waste and meet EPA's regulations. Under the WIPP Compliance Criteria (40 CFR 194), DOE must immediately report to EPA significant changes to activities or conditions at WIPP, especially those that could lead to radioactive releases that violate EPA's regulations. For less significant changes, EPA requires that DOE submit an annual WIPP Change Report, which documents any changes made to the WIPP program during the previous year. EPA reviews each Change Report to determine whether any of the changes are significant and could potentially affect WIPP's performance.

On November 19, 2002, DOE submitted its fifth annual WIPP Change Report detailing changes that occurred between September 16, 2001, and September 15, 2002. The majority of the reported changes were to written plans and procedures used to maintain compliance with the Certification. We requested supplemental information concerning waste characterization inspections at various sites and an updated waste inventory summary. We completed our review and determined that the changes were not significant and that the 2002 Annual Change Report was complete. We provided the results to DOE in August 2003. Our request for information, as well as previous WIPP Change Reports, can be found in our recertification Docket A-98-49 under Categories II-B2 and II-B3.

Lastly, DOE requested and EPA granted a change of reporting dates for future Annual Change Reports. DOE proposed to alter the schedule to reflect a reporting period of July 1-June 30 of the next year. EPA concurred that the revised reporting dates would accommodate more detailed information and analyses.

Waste Generator Site Inspections: An Overview

This provides an overview of the process that EPA uses to approve waste characterization activities at DOE WIPP waste generator sites. It takes into account the revisions to 40 CFR Part 194 that will be finalized in early 2004.

Introduction

EPA regulations governing disposal of transuranic (TRU) waste at the Waste Isolation Pilot Plant (WIPP) require that EPA inspect and approve waste characterization activities at the Department of Energy (DOE)'s TRU waste sites. Before waste is ever sent to WIPP for disposal, EPA conducts inspections at the generator sites to verify that the Department of Energy's (DOE) waste characterization program in place can measure and track how much waste goes to WIPP and what that waste contains. EPA staff then conduct inspections annually, or more frequently in cases where DOE seeks approval of changes to waste characterization components warranting new inspections. This document provides a general overview of EPA's inspections program.

What Does EPA Inspect?

EPA looks at TRU waste site characterization programs to ensure that all waste going to WIPP will meet disposal requirements (i.e., the WIPP Certification Decision). EPA regulations require that generator sites quantify and track the amount and type of material in each TRU waste drum destined for disposal at the WIPP. If, after inspection, EPA does not approve the characterization process, the site cannot dispose of the waste at WIPP. EPA validates that the DOE's equipment can detect what it is intended to detect, that it is working properly, and that it is operated by properly trained and qualified staff. EPA also seeks assurance that appropriate programs are in place and meet national standards to verify the quality of all work.

How Does EPA Conduct These Inspections?

Before visiting a site, EPA reviews documents and records to understand site procedures and to identify items and activities that are most important to evaluate in person. EPA visits the generator sites to observe operations in progress, inspect equipment, interview operators, and review procedures. Depending on the size and complexity of the operation, multiple inspectors will work together to ensure important aspects of the program are inspected.

Who are the Personnel at These Inspections?

EPA sends staff and contractors with technical expertise and experience suitable for the scope of the inspection. EPA inspectors are expert in individual areas of the waste characterization process. There are also other parties who conduct inspections to evaluate compliance with other requirements or regulations. While these activities are independent of EPA's waste characterization inspections, they are often coordinated to coincide with EPA inspections. Quality Assurance (QA) personnel from DOE's Carlsbad Field Office perform a QA review of site activities; DOE QA inspectors determine whether the site has properly implemented DOE's waste characterization procedures and whether the resulting data meets the data quality objectives. EPA oversees DOE's QA activities and will occasionally observe QA reviews at sites. Staff from New Mexico Environment Department, a State agency regulating disposal of TRU waste mixed with hazardous waste at WIPP, evaluate

Waste Generator Sites

The waste intended for disposal at WIPP is currently at about 15 DOE sites across the U.S. Some of the waste was produced through past processing of nuclear materials and production of atomic weapons. Other waste is being generated as these sites are cleaned up.

Since the WIPP began operation in 1998, EPA has approved waste characterization processes at the following DOE generator sites:

- **Hanford Site**, Washington
- **Idaho National Engineering and Environmental Laboratory**
- **Los Alamos National Laboratory**, New Mexico
- **Rocky Flats Environmental Technology Site**, Colorado
- **Savannah River Site**, South Carolina

EPA has also approved several sites to use the Central Characterization Project (CCP), a mobile characterization facility that DOE has developed to assist TRU waste generator sites with complex waste characterization activities:

- **Argonne National Laboratories-East**, Illinois
- **Nevada Test Site**
- **Savannah River Site**

Sites with pending EPA approval include:

- **Oak Ridge National Laboratory**, Tennessee
- **Other small generator/storage sites**
- **CCP – Los Alamos National Laboratory**
- **CCP – Hanford**

whether the site complies with RCRA permit related hazardous waste characterization requirements. Representatives of the Environmental Evaluation Group, an independent non-profit technical oversight organization, may observe inspections related to WIPP.

When Does EPA Conduct Inspections?

Every generator site requires an initial baseline inspection by EPA before it is approved to ship waste to WIPP. EPA inspectors evaluate equipment, procedures, and personnel training/experience related to a range of waste characterization components. If they are adequate to characterize waste for disposal at WIPP, EPA issues a "baseline approval" that allows the site to dispose of waste at WIPP (once shipping and other requirements are met). The baseline approval specifies any limitations on waste characterization or disposal (such as restrictions on what waste streams may be disposed) and any potentially significant changes in a site's waste characterization program that will require additional EPA inspections and approvals. These changes and/or expansions will be assigned to one of two categories ("tiers"), depending on the required level of notification and approval outlined in the site's initial baseline approval. Tier 1 waste characterization activities at a site will have more stringent reporting requirements (e.g., require notification by DOE and approval by EPA prior to shipment of waste to the WIPP) and will most likely require additional inspections whenever any changes to that activity are made. Tier 2 activities will have more moderate reporting requirements and EPA may approve changes to certain activities without a follow-up inspection (i.e., desktop review and approval of certain technical documents). EPA will specify the limitations associated with the as-

signed tier and suggest the type of information needed for the Agency's review and approval. DOE will report any changes in equipment, processes, or personnel, based on the site's tier level, and certain changes must be reported to EPA before their implementation. EPA will then decide whether or not a follow-up inspection is necessary to confirm and verify the adequacy of any changes to the site's waste characterization program. The scheduling of inspections is not done on a set basis, but according to availability of inspectors and any other parties and the readiness of equipment for inspection. Advance notice by EPA varies accordingly. In addition, EPA is free to conduct inspections at any other time it deems that inspections of a particular site may be warranted.

What is the Result of These Inspections?

EPA's goal for waste characterization inspections is to verify that the waste characterization processes at the site function adequately. After an inspection, EPA produces an inspection report to describe its findings. Findings that a specific item or activity is deemed inadequate usually require action by DOE to correct the problem and take steps to ensure it does not recur. For example, a few sites we might find that the tracking of Acceptable Knowledge (AK) data is inconsistently formatted and/or incomplete. (AK is the detailed history of the waste contents, processes, and origination.) If problems with the AK data are identified, EPA does not approve the waste for disposal at WIPP. Once DOE corrects the problems, EPA's inspection team returns to verify that the AK data is adequate. If no further problems are discovered, the waste can be approved for disposal.

A typical problem identified during Quality Assurance (QA) program inspections has to do with the independence of the sites' QA Organiza-

tions. The Nuclear Quality Assurance standards require that each QA Organization "report to a management level such that required authority and organizational freedom are provided, including sufficient independence from cost and schedule considerations." However, the EPA audit teams find instances where the QA Organizations have not been provided this degree of independence. In these cases, EPA returns to the sites to verify that the problem is corrected and the QA Organizations are provided adequate independence.

For our initial baseline inspections, the inspection report will include proposed tier designations for specific aspects and components of the site's waste characterization program. This proposed tiering scheme will outline the changes and expansions to certain waste characterization activities that will most likely trigger additional inspections by EPA.

What is DOE's Role in the Inspection Process?

DOE notifies EPA of a site's desire to characterize TRU waste for the WIPP and its readiness to undergo a baseline inspection. DOE also must notify EPA when it makes changes to an approved site program. (Depending on their significance, and how they were categorized in the baseline approval, these changes could prompt additional inspections, or could simply be reviewed and approved by EPA after implementation). DOE provides all relevant documents (including site-wide plans and equipment-specific procedures) containing the site's waste characterization plans and data quality assurance procedures. DOE must provide full access to personnel, equipment, and information related to an inspection. Following inspection and approval by EPA, DOE is responsible for correcting findings and operating its sites in accordance with these certified processes.

What Information Will EPA Provide to the Public?

EPA makes available to the public a written statement of the scope of an inspection, as well as site-wide plans provided by DOE which form the basis for our site visit. EPA also makes public the inspection report which documents the results of our inspection, including any problems identified during the visit. For the initial baseline inspection at a site, EPA will also issue a Federal Register notice after the inspection but before issuing any approval for the site. The notice will state the results of the inspection, EPA's proposed approval or disapproval, and any restrictions on the approval. It will also describe what changes or expansions in the waste characterization program changes will require further EPA inspections and approvals. Potentially significant changes will be assigned to one of two categories ("tiers"), depending on the required level of notification and approval. EPA will accept and consider public comments on all aspects of the baseline approval.

Once a site has been approved and waste characterization tiers have been established, EPA will announce follow-up inspections on EPA's WIPP website. Inspection reports for these follow-up inspections will continue to be placed in EPA's WIPP dockets as well.

EPA may also decide to revise the tiering designations at any site following the initial Baseline Compliance Decision. This decision will be based on a variety of factors. Some sites may have a harder time converting to the more robust inspections regime, and certain aspects of their WC program that were strong in the past may need more intense scrutiny. Conversely, certain sites will undoubtedly improve their overall performance as they become accustomed to the new system, and certain

aspects of their WC program will subsequently require less attention.

If EPA believes that a change in tiering designation is necessary for any aspect of a site's waste characterization program after the initial baseline decision, the Agency will notify the public through our website and dockets.

Changing an activity to a more stringent tier (i.e., additional DOE reporting requirements for that particular waste characterization component or activity) will be effective immediately and the site will be expected to operate under the more stringent requirements without delay.

Before moving an activity to a less stringent tier, EPA will solicit public

comment. The site will continue to operate under the more stringent tier designation until public comment can be considered. The basis to change the level of oversight for an activity (i.e., tier designation) will be described in our inspection reports.

How Can You Get Involved?

You can stay up-to-date on EPA's inspection activities by visiting our WIPP website, where we will post updates and other information regarding any upcoming inspections and site-related decisions. Also, when EPA is considering whether to approve new sites to dispose of waste at WIPP, you can provide comments on our proposed decision and have input regarding what future program changes at the site merit a greater degree of oversight by EPA in the future. As previously mentioned, EPA will issue a Federal Register notice after the initial baseline inspection at each site and open an official comment period. Instructions on submitting comments for these actions will be included in each of these notices and will be posted on the WIPP website. Information about the scope and results of follow-up inspections will also be announced on the site and in-

spection reports will continue to be sent to our WIPP dockets.

As always, EPA will accept comments and questions on our inspections or other WIPP program activities at any time. Please feel free to e-mail us at radiation.questions@epa.gov.

ACRONYMS:

EPA Environmental Protection Agency
DOE US Department of Energy
TRU Transuranic
CCP Central Characterization Project
QA Quality Assurance
RCRA Resource Conservation and Recovery Act

WIPP Dockets Locations

EPA Docket Center (EPA/DC)
Air and Radiation Docket
EPA West, Mail Code 6102T
1200 Pennsylvania Ave., N.W.
Washington, DC 20460
(202) 260-7548
(all dockets)

Carlsbad Public Library
101 S. Halagueno
Carlsbad, NM 88220
(505) 885-6776
(all dockets)

Zimmerman Library
Government Publications
University of New Mexico
Albuquerque, NM 87131
(505) 277-5441
(all dockets)

Fogelson Library
College of Santa Fe
1600 St. Michaels Drive
Santa Fe, NM 87505
(505) 473-6576
(Docket A-93-02 only, EPA's WIPP Certification Decision)

New Mexico State Library
1209 Camino Carlos Rey
Santa Fe, NM 87505
(505) 476-9717
(Docket A-98-49 only, EPA's WIPP Recertification Decision)

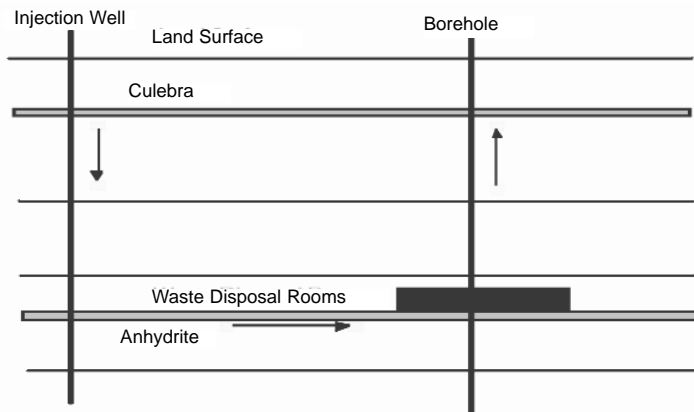
A Look at Human Intrusion into the WIPP, Focus on Fluid Injection

In the last Bulletin, we discussed the role of human intrusion scenarios in assessing the performance of the WIPP. This time we will focus on a particular human intrusion event that received much attention during certification: Fluid Injection. Fluid injection is the process of pumping pressurized fluid through a borehole into the subsurface.

There are a number of reasons why fluid injection takes place: to dispose of unwanted fluids such as water produced when oil is extracted, to dispose of waste water, to enhance oil recovery, and to dissolve salt to produce potash or to create a cavity to store oil or gas.

Water used in oil production is usually injected beneath the Salado salt formation in the Delaware Mountain Group formations. The Delaware Mountain Group is more than 2000 feet directly below the WIPP disposal level. The concern at WIPP is that, under some potential scenarios, injected brine could migrate from the injection zone, flow into the WIPP disposal rooms, and transport radionuclides to various exit pathways, such as other boreholes or through other geological formations adjacent to the WIPP rooms.

During the original certification, extensive analysis was done by both EPA and DOE to evaluate the potential impact of this drilling practice. The EPA concluded that this scenario did not



need to be included in the certification performance assessment because Fluid Injection does not occur near WIPP, and if it did occur, it would not cause releases greater than those already considered in the performance assessment results.

EPA will require DOE to reevaluate this scenario for the recertification in 2004 to ensure that it is not now occurring near WIPP. EPA will also perform its own review to determine if the methodology used in the original certification assumptions still holds true today. If this is not the case, then fluid injection may need to be included in the new performance assessment calculations.

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